K003514 p.1 of 2

FEB 12 2001

510(k) Summary

1.0 SUBMITTER INFORMATION

1.1 Submitter: SHIMADZU MEDICAL SYSTEMS
20101 South Vermont Ave.
Torrance, CA 90502-1328
PH: 310-217-8855
FX: 310-217-8869

1.2 Contact: Masaaki Shibata

1.3 Date : November 10, 2000

2.0 DEVICE NAME

2.1 Proprietary Name: SDU-2200

2.2 Common Name: : Ultrasound Imaging System

2.3 Classification: Ultrasonic Pulsed Doppler Imaging System
FR # 892.1550, Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System
FR # 892.1560, Product Code 90-IYO
Diagnostic Ultrasound Transducer
FR # 892.1570, Product Code 90-ITX

2.4 Predicate Device: GE Logiq 500 (K991611, 6/9/99)

3.0 DEVICE DESCRIPTION

The SDU-2200 is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Color mode, Continuous Doppler mode, or in a combination of modes.

4.0 INTENDED USE

The SDU-2200 is intended for the following applications:

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

5.0 SAFETY CONSIDERATIONS

SDU-2200 has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Mr. Masaaki Shibata
Ultrasound Project Manager
Shimadzu Medical Systems
20101 South Vermont Ave.
TORRANCE CA 90502-1328

Re: K003514
SDU-2200 Diagnostic Ultrasound System
Dated: November 10, 2000
Received: November 14, 2000
Regulatory Class: II
21CFR §892.1550/Procode: 90 IYN
21CFR §892.1560/Procode: 90 IYO
21CFR §892.1570/Procode: 90 ITX

Dear Mr. Shibata:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SDU-2200 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

L040-075U 5 – 10 MHz Linear array
L040-120U 8 – 15 MHz Linear array
L070-075U 5 – 10 MHz Linear array
L072-050U 3.5 – 7 MHz Linear array
VA13R-035U 2.5 – 5 MHz Convex array, 13 mmR
VA13R-050U 3.5 – 6 MHz Convex array, 13 mmR
VA20R-035U 2.5-5.5 MHz Convex array, 20 mmR

VA40R-035U 2 – 5 MHz Convex array, 40 mmR
VA40R-035HU 2 – 5 MHz Convex array, 40 mmR
VA57R-0375WU 2 – 5.5 MHz Convex array, 57 mmR
VA57R-0375HU 2 – 5.5 MHz Convex array, 57 mmR
S017-035U 2-5 MHz Sector array
S011-050U 3.5-7 MHz Sector array
TV11R-055U 4 - 8 MHz Transvaginal convex array, 11 mmR
UB10R-065U 4 - 8 MHz Transrectal biplane convex array,10 mmR

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 1 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, system

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N	N	N	N	N	N		
*Small Organ (Specify) **		N	N	N		N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal		N	N	N		N	N	N	N		
Transvaginal		N	N	N		N	N	N	N		
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N		
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N		
Musculo-skeletal Superficial		N	N	N		N	N	N	N		
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, L040-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N		
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N		
Musculo-skeletal Superficial		N	N	N		N	N	N	N		
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
* Thyroid, Testicles, Breast
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Legum

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 3 of 16 .

510(k) Number (if known) : _____.
Device Name : Diagnostic Ultrasound System SDU-2200, L040-120U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N		
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N		
Musculo-skeletal Superficial		N	N	N		N	N	N	N		
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
* Thyroid, Testicles, Breast
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 4 of 16 .

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, L070-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N		
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N		
Musculo-skeletal Superficial		N	N	N		N	N	N	N		
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
* Thyroid, Testicles, Breast
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 5 of 16 .

510(k) Number (if known) : _____.
Device Name : Diagnostic Ultrasound System SDU-2200, L072-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N		
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N		
Musculo-skeletal Superficial		N	N	N		N	N	N	N		
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
* Thyroid, Testicles, Breast
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyerm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 6 of 16 .

510(k) Number (if known) : _____.
Device Name : Diagnostic Ultrasound System SDU-2200, VA13R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement

510(k) Number (if known) : _____.
Device Name : Diagnostic Ultrasound System SDU-2200, VA13R-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N		
Abdominal		N	N	N		N	N	N	N		
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N		
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 8 of 16 .

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, VA20R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 9 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, VA40R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 10 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, VA40R-035HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1

David A. Jegorm

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 11 of 16 .

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, VA57R-0375WU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 12 of 16 .

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, VA57R-0375HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 13 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, S017-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

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510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 14 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, S011-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal				N		N	N				
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N	N	N	N	N	N		
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N		
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyon

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)
Ultrasound Device Indications Statement Page 15 of 16 .

510(k) Number (if known) : _____ .
Device Name : Diagnostic Ultrasound System SDU-2200, TV11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N		
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		N	N	N		N	N	N	N		
Transvaginal		N	N	N		N	N	N	N		
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

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510(k) Number K003514

K003514

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 16 of 16 .

510(k) Number (if known) : _____ .

Device Name : Diagnostic Ultrasound System SDU-2200, UB10R-065U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		N	N	N		N	N	N	N		
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

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510(k) Number K003514